

Docket No.: 066742-0014

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|           |   |  |
|-----------|---|--|
| Applicant | : Smith, Terry, et al.  | Customer No.: 41552  |
| Appl. No. | : 10/046,651  | Confirmation No.: 3673   |
| Filed     | : October 19, 2001  | CERTIFICATE OF MAILING BY EXPRESS MAIL(37 CFR § 1.10)  |
| Title     | : DETECTION OF ANTIBODY MEDIATED<br>INFLAMMATORY AUTO-IMMUNE<br>DISORDERS | "Express Mail" Mailing Label Number EV 540266835 US<br>I hereby certify that this paper or fee is being deposited with the United<br>States Postal Service "Express Mail Post Office to Addressee" service<br>under 37 CFR § 1.10 on the date indicated above and is addressed to<br>Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on<br>August 10, 2004. |
| Grp./A.U. | : 1644  | <i>Cris Johnson</i>  |
| Examiner: | : Patrick J. Nolan  | Cris Johnson   |
|           |   |  |

**RESPONSE TO RESTRICTION REQUIREMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Noting the Office Action of May 26, 2004 wherein restriction has been required,  
Applicants hereby elect Group VI (claims 13-14 and 17-19) for prosecution in the above-  
identified application.

Claims 1-19 are pending. The Office alleges that the claims are directed to six distinct  
and independent inventions as follows:

- Group I : Claims 1, 2, 5, 6 and 9, drawn to a method of treating antibody  
mediated autoimmune disorders with an IL-16 activity inhibitor;
- Group II : Claims 1 3, 5, 7 and 9, drawn to a method of treating antibody  
mediated autoimmune disorders with a RANTES activity inhibitor;
- Group III : Claims 1, 4, 5, 8 and 9, drawn to a method of treating antibody  
mediated autoimmune disorders with a combination or RANTES  
and IL-16 activity inhibitors;

- Group IV : Claims 13-15 and 18-19, drawn to a method of detecting antibody-activated fibroblasts by detecting IL-16;
- Group V : Claims 13-14, 16 and 18-19, drawn to a method of detecting antibody activated fibroblasts by detecting RANTES; and
- Group VI : Claims 13-14 and 17-19, drawn to a method of detecting activated fibroblasts by detecting IL-16 and RANTES.

The Office Action is requiring restriction to a single disclosed invention under 35 U.S.C.

§121. Applicants traverse the Restriction Requirement for the reasons stated below.

Nevertheless, in order to be responsive to the Office Action, Applicant elects the claim of Group VI, claims 13-14 and 17-19, directed to a method of detecting antibody-activated fibroblasts in a patient by measuring a combination of IL-16 and RANTES levels in a biological sample. Applicants reserve the right to pursue prosecution of the non-elected claims in a later filed application claiming the benefit of priority of the above-identified Application.

Applicants respectfully point out that two separate requirements must be met in order for restriction to be proper. First, the inventions must be independent or distinct. Secondly, there must be a serious burden on the Examiner if restriction is required. See, for example, MPEP 803 (Restriction- When Proper), which states, in part:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Page 800-3; emphasis added.

Thus, it is not sufficient for an Examiner to assert that patentably distinct inventions are present in order to restrict an application. There also must be a serious burden on the Examiner to search and examine the entire application. For the reasons set forth below, Applicants

respectfully submit that the burden of searching and examining the method claims of Groups IV through VI together has not been sufficiently established for the restriction to be proper.

Applicants traverse the Restriction Requirement with respect to the division of the claims of Groups IV, V and VI. The Office asserts that the claimed methods of these groups of inventions represent patentability distinct subject matter. The invention of Groups IV, V and VI are alleged to differ in respect to applicable prior art, which is asserted to differ with regard to whether IL-16 activity, RANTES activity or a combination thereof is detected. The Office concludes, based on the above, that the inventions of Groups IV, V and VI have acquired a separate status based on their different classifications and divergent subject matter and that each group would require a separate search. Applicants submit that the art related to measuring IL-16 levels and RANTES levels, necessarily will overlap with the art related to measuring a combination of IL-16 and RANTES levels.

Applicants submit that, while the claims of Groups IV, V and VI are patentably distinct, a thorough search of the elected claims of Group VI directed a method of detecting antibody-activated fibroblasts in a patient by measuring a combination of the levels of IL-16 and RANTES in a biological sample will include art relevant to the claims of Groups IV and V, directed a method of detecting antibody-activated fibroblasts in a patient by measuring the level of IL-16 and RANTES, respectively, in a biological sample. Groups IV, V and VI also share a common base claim (claim 13), which is a markush-style claim directed to a method of detecting antibody-activated fibroblasts in a patient by measuring a combination of the levels of an analyte chosen from the groups consisting of IL-16, RANTES and combinations thereof in a biological sample. Therefore, rejoinder is respectfully requested.

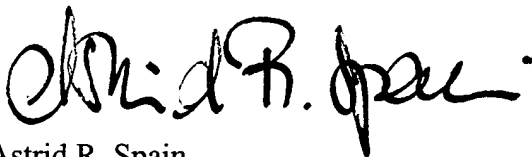
For the reasons set forth above, Applicants request reconsideration and removal the Restriction Requirement with regard to Groups IV, V and VI. Again, examination of Groups VI and V in addition to elected Group VI would not pose a serious burden on the Examiner because art related to measuring IL-16 levels and RANTES levels, necessarily will overlap with the art related to measuring a combination of IL-16 and RANTES levels. Applicants note that the inventions of Groups IV, V and VI are further classified together in class 435, subclass 7.1.

If rejoinder is denied for all or some of the restricted claims, Applicants respectfully requests a "second-eye review" as now implemented under the Restriction Practice Action Plan. Under the Action Plan, rejoinder practice is viewed favorably when examination of claims together would not pose a serious burden on the Examiner.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

MCDERMOTT WILL & EMERY LLP

A handwritten signature in black ink, appearing to read "Astrid R. Spain", with a stylized flourish at the end.

Astrid R. Spain  
Registration No. 47,956

4370 La Jolla Village Drive, Suite 700  
San Diego, CA 92122

858.535.9001 ARS:cej  
Facsimile: 858.597.1585  
**Date: August 10, 2004**